K062156

P 1 of 2

OSSTEM Implant Co., Ltd.
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Phone: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

OCT 20 2006

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 25, 2006

1. Company and Correspondent making the submission:

	Company
Name	Osstem Implant Co., Ltd.
Address	#507-8 Geoje3-Dong Yeonje-GuBusan, 611-804, Korea
Phone	+82 51-850-2573
Fax	+82 51-861-4693
Contact	Sung Ryul, Kim

2. Device:

Proprietary Name – Super Orthodontic Screw
Common Name – Dental Implant
Classification Name – Endosseous dental implant

3. Predicate Device:

Osteomed Orthodontic Screw System, Osteomed L.P., K031936
Dual Top Anchor System Screws, Jeil Medical Corporation, K033767

4. Classifications Names & Citations:

21CFR 872.3640, DZE, Endosseous dental implant, ClassII

5. Description:

The Super Orthodontic Screw is a dental implant system made of titanium metal intended to be used as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is 1.6 and 1.8 mm in screw diameter and 6, 8, 10, 12mm in length. It is made of Titanium 6Al-4V alloy(ASTM F 136-98). The surface of the screw is non-treated and that of head is TiN coated. There is a hole in the screw head through which a wire can be passed to fix the mandible and maxilla in orthodontic treatment. It is supplied non-sterile and must be sterilized prior to use by Steam heat sterilization.

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6. Indication for use:
Super Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.

7. Contra-indications:
Osteoporosis
Advanced diabetes
Metal allergy

8. Review:
Super Orthodontic Screw has the same device characteristics as the predicate device. Material, design and use concept is similar.

Super Orthodontic Screw has been subjected to extensive safety, performance, and product validations prior to release. Safety tests have been performed to ensure the devices comply to applicable industry and US regulations.

An extensive review of literature pertaining to the safety and biocompatibility of Super Orthodontic Screw has been conducted. Appropriate safeguards have been incorporated in the design of Super Orthodontic Screw.

9. Conclusions:
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that Super Orthodontic Screw is safe and effective and substantially equivalent to predicate devices as described herein.

10. Osstem Implant Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2006

Osstem Implant Company Limited
C/O Ms. Cathryn Cambria
Consultant
Cambria Regulatory Consulting, Incorporated
5536 Trowbridge Drive
Dunwoody, Georgia 30338

Re: K062156
Trade/Device Name: Super Orthodontic Screw
Regulation Number: 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 2, 2006
Received: October 5, 2006

Dear Ms. Cambria:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276.0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K062156

510(k) Number K _____

Device Name: Super Orthodontic Screw

Indication for use: Super Orthodontic Screw is indicated for use as a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth. It is used temporarily and is removed after orthodontic treatment has been completed. Screws are intended for single use only.

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21CFR801 Subpart D) (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kai Mulay for MSR
(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K062156